Decision Memo for Intensive Cardiac Rehabilitation (ICR) Program - Dr. Ornish's Program for Reversing Heart Disease (CAG-00419N)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) has determined that the Ornish Program for Reversing Heart Disease meets the intensive cardiac rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act and in our regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/MedicareApprovedFacilitie/.

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Decision Memo

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SUBJECT:	Coverage Decision Memorandum for Intensive Cardiac Rehabilitation (ICR) Program - Ornish Program for Reversing Heart Disease (CAG-00419N)
DATE:	August 12, 2010

I. Decision

The Centers for Medicare and Medicaid Services (CMS) has determined that the Ornish Program for Reversing Heart Disease meets the intensive cardiac rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act and in our regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/MedicareApprovedFacilitie/.

II. Background

Cardiac rehabilitation (CR) was developed in the 1950s from the concept of early mobilization after acute myocardial infarction (Pashkow, 1993). The standard of care prior to the widespread adoption of CR was bedrest and inactivity after acute myocardial infarction (Forman, et al., 2000). In the 1970s, cardiac rehabilitation developed into highly structured, physician supervised, electrocardiographically-monitored exercise programs. However, the programs consisted almost solely of exercise alone (Ades et al., 2000). Foreman et al. (2000) states that "over subsequent years, CR broadened beyond exercise into a composite of cardiac risk modification. Lipid, blood pressure and stress reductions, smoking cessation, diet change, and weight loss were coupled to goals of exercise training."

The Ornish Program for Reversing Heart Disease (also known as the Multisite Cardiac Lifestyle Intervention Program, Multicenter Cardiac Lifestyle Intervention Program and the Lifestyle Heart Trial program) was initially described in the 1970's and incorporates comprehensive lifestyle modifications including exercise, a low-fat diet, smoking cessation, stress management training, and group support sessions. Over the years, the Ornish program has been refined but continues to focus on these specific risk factors.

Although Medicare has covered CR for certain patients since 1982, a new part B benefit was established for ICR in §1861(eee)(4)(A) effective for items and services furnished on or after January 1, 2010.

III. Statutory and Regulatory Background

The objective of this national coverage analysis is to determine if the Ornish program meets the new statutory and regulatory requirements to be approved as a Medicare ICR program. Medicare internally generated this analysis in order to determine whether the Ornish program meets the ICR program requirements and would be eligible for Medicare coverage.

Intensive cardiac rehabilitation (ICR) refers to a physician-supervised program that furnishes cardiac rehabilitation services more frequently and often in a more rigorous manner. As required by §1861(eee)(4)(A) of the Social Security Act, an ICR program must show, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcomes. To implement this provision, CMS added 42 C.F.R. §410.49. This section was added through rule making in the CY 2010 Physician Fee Schedule Final Rule. See 74 Fed. Reg. 62004-62005 (November 25, 2009).

As required by §1861(eee)(4)(A)(i) of the Act, to be approved as a Medicare ICR program, a program must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients: (1) positively affected the progression of coronary heart disease; (2) reduced the need for coronary bypass surgery; and (3) reduced the need for percutaneous coronary interventions. As required by §1861(eee)(4)(A)(ii) of the Act, an ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and (6) the need for cholesterol, blood pressure, and diabetes medications. ICR programs must be approved through the NCD process to ensure that they demonstrate these accomplishments (42 C.F.R. §410.49(c)).

Intensive cardiac rehabilitation program sessions are limited to 72 one-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks (§1861(eee)(4)(C); 42. C.F.R. §410.49(f)(2)).

Benefit Category

Medicare is a defined benefit program. An item or service must fall within a benefit category under Part A or Part B as a prerequisite to Medicare coverage. Congress has specifically authorized coverage of ICR under Part B of the Medicare program (§1861(eee)(4) of the Social Security Act).

IV. Timeline of Recent Activities

November 17, 2009	Internally generated NCA. Initial 30-day public comment period begins.
December 17, 2009	Initial 30-day public comment period ends.
May 14, 2010	Proposed decision memorandum posted. 30-day public comment period begins.

V. FDA

The Ornish program is not subject to FDA oversight.

VI. General Methodological Principles

When making national coverage determinations concerning ICR programs, CMS evaluates relevant peer-reviewed published research to determine whether or not the ICR program meets the criteria required in §1861(eee) of the Act.

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. Public comments that contain personal health information will not be made available to the public. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

In this analysis, we evaluated the impact of the Ornish program on the following health outcomes, as listed in §1861(eee): (1) the progression of coronary heart disease; (2) reduction in the need for coronary bypass surgery; and (3) reduction in the need for percutaneous coronary interventions. We also evaluated the effect of ICR on the following cardiac risk factors: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and (6) the need for cholesterol, blood pressure, and diabetes medications.

Literature Search

CMS evaluated peer-reviewed, published research including clinical research studies, technology assessments, guidelines and reviews that focused on heart disease and were published from January, 1980 to January, 2010. General keywords included cardiac rehabilitation, exercise, and the Ornish program. Abstracts without a complete publication were excluded. Using these general parameters, nine original studies and one systematic review were found.

B. Discussion of evidence reviewed

1. Evidence Question

For this analysis, we addressed the following question:

Does the Ornish Program for Reversing Heart Disease (also known as the Multisite Cardiac Lifestyle Intervention Program, Multicenter Cardiac Lifestyle Intervention Program and the Lifestyle Heart Trial program) meet the requirements set forth in §1861(eee)(4) for an ICR program:

(1) positively affected the progression of coronary heart disease;
(2) reduced the need for coronary bypass surgery; and
(3) reduced the need for percutaneous coronary interventions?

As required by §1861(eee)(4)(A)(ii) of the Act, an ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and (6) the need for cholesterol, blood pressure, and diabetes medications.

2. External Technology Assessment

Roberts CK, Barnard RJ. Effects of exercise and diet on chronic disease. J Appl Physiol 2005;98:3–30.

Roberts and Barnard reported the results of a systematic review to: "1) discuss the effects of exercise and diet in the prevention of chronic disease, 2) highlight the effects of lifestyle modification for both mitigating disease progression and reversing existing disease, and 3) suggest potential mechanisms for beneficial effects." The review focused on lifestyle modification programs that included physical activity and dietary interventions. Search and inclusion criteria were not reported. For coronary heart disease, the authors summarized: "Physical inactivity and dietary factors both contribute vitally to atherosclerosis and consequent CAD (coronary artery disease). Studies indicate that inactivity may be as predictive of CAD risk as conventional risk factors, exercise training may improve endothelial function and is superior to percutaneous angioplasty for short-term survival. Additionally, several dietary factors such as fiber, fat (amount and type), glycemic load, and fruit and vegetable consumption appear to significantly modulate CAD risk. Combined exercise and diet interventions mitigate atherosclerosis progression and may in fact induce plaque regression and/or improve myocardial flow reserve. These benefits are, at least in part, due to reductions in plasma lipids, lipid oxidation, and inflammation. Improvements in risk factors with diet may, in some instances, be as great as with statin therapy, and lifestyle interventions combined with statin therapy possess additive effects on lipid lowering. Moreover, although obesity contributes to CAD, risk can be modified independent of large changes in weight." Specifically for studies based on the Ornish program, they reported: "In the Lifestyle Heart Trial, 48 patients were randomized to either intensive dietary and lifestyle changes, including a whole-food vegetarian diet with 10% of energy from fat, aerobic exercise, stress management training, smoking cessation, and group social support, or usual care, consisting of an NCEP Step I diet. After 1 yr, the experimental group showed more favorable changes in angina frequency and quantitative coronary arteriography. After 5 yr of follow-up, the experimental group exhibited a relative reduction in diameter stenosis of 7.9% compared with a 27.7% progression in the control group (281). The risk ratio for a cardiac event in the control group compared with the experimental group was 2.47."

3. Internal Technology Assessment

Daubenmier JJ, Weidner G, Sumner MD, Mendell N, Merritt-Worden T, Studley J, Ornish D. The contribution of changes in diet, exercise, and stress management to changes in coronary risk in women and men in the Multisite Cardiac Lifestyle Intervention Program. Ann Behav Med 2007;33:57–68.

Daubenmier and colleagues used a case series/quasi-experimental design to look at 3-month changes in health behaviors, coronary risk and psychosocial factors in a population of 869 nonsmoking individuals. All participants had a documented history of coronary heart disease, defined by one of the following criteria: ischemia documented with noninvasive testing (e.g. nuclear imaging); cardiac catheterization showing CHD; history of percutaneous coronary intervention (PCI), coronary bypass surgery (CABG) or myocardial infarction; eligibility for PCI or CABG. Also, they were all enrolled in the health-insurance-based Multisite Cardiac Lifestyle Intervention Program (MCLIP), designed by Ornish and colleagues. The intervention took place at 22 program sites in four states, and included the following components: cardiac risk factor modification (e.g. diet counseling/behavioral intervention), exercise, psychosocial and outcomes assessment, as well as stress management. The exercise component included both onsite sessions, supervised by "trained professionals," and exercise completed at home. The intensity of the program is as follows: aerobic exercise for 3 hours per week at minimum for 3 months, regularly scheduled strength training exercises, stress management techniques, and group support sessions. Statistical methods used included: independent-sample t-tests for continuous variables and chi-square analysis for dichotomous variables in comparing baseline differences; analysis of variance and hierarchical multiple regression analyses in looking at changes in health behaviors and in outcome measures.

Mean age was 59 in men, 60 in women, and many participants had comorbid diabetes (26% of 576 men, and 31% of 293 women). Results showed significant improvements in health behaviors and in several coronary risk factors. In comparing baseline to 3-month follow-up values, the authors noted significant improvements for the following coronary risk factors (among others): weight (kg) 95.9 to 90.4 in men, 83.2 to 79.1 in women, p (Time) = 0.001 for combined group; systolic blood pressure (mm Hg) 132 to 120 in men, 131 to 122 in women, p (Time) = 0.001; diastolic blood pressure (mm Hg) 78 to 71 in men, 76 to 71 in women, p (Time) = 0.001; LDL-C (mg/dL) 94 to 78 in men, 107 to 92 women, p (Time) = 0.001; triglycerides (mg/dL) 175 to 156 in men, 185 to 183 in women, p (Time) = 0.001; and hemoglobin A1c (among patients with diabetes) 7.2 to 6.4 in men, 8.0 to 7.1 in women, p (Time) = 0.001. Significant improvement in psychosocial factors such as depressive symptoms was also noted by the authors. Finally, a multiple regression analysis showed that 3-month improvements in stress management, exercise and dietary fat intake were significantly associated with 3-month improvements in coronary risk and psychosocial factors.

The authors concluded that insurance companies can successfully implement a multicomponent secondary prevention program for CHD at multiple hospital sites across the country. The results indicate that "the dietary, exercise, and stress management components are individually, additively, and interactively related to improvements in multiple coronary risk and psychosocial factors."

Frattaroli J, Weidner G, Merritt-Worden TA, Frenda S, Ornish D. Angina pectoris and atherosclerotic risk factors in the Multisite Cardiac Lifestyle Intervention Program. Am J Cardiol 2008;101:911–918.

Frattaroli and colleagues reported the results of an observational study "to examine angina reduction in both men and women who are making comprehensive lifestyle changes." The study reported on 1,152 patients with coronary artery disease enrolled in the Multisite Cardiac Lifestyle Intervention Program from September 1998 to June 2006. The Multisite Cardiac Lifestyle Intervention Program consisted of individually prescribed exercise for a minimum of 3 hours per week for a minimum of 30 minutes per session. The program also incorporated a very low fat diet, strength training, stress management and group support sessions. Primary outcome was frequency and severity of angina assessed using the Canadian Cardiovascular Society guidelines. Patients were eligible if they were diagnosed with coronary artery disease defined as: "(1) ischemia documented using noninvasive testing, such as exercise testing, nuclear imaging, echocardiogram, or other tests clearly showing ischemia; (2) cardiac catheterization showing CAD; (3) a history of percutaneous coronary intervention, coronary bypass surgery, or myocardial infarction; or (4) eligibility for percutaneous coronary intervention or coronary bypass surgery." Exclusions included: "(1) ischemic left main CAD with an obstruction > 50% and (2) significant (> 70%) proximal left anterior descending artery and proximal left circumflex artery disease and an ejection fraction < 50%." Mean age was approximately 60 years. Men compromised 66% of the study. Follow up was 12 weeks. The McNemar-Boker test was used for outcome analysis.

The authors reported: "At 12 weeks, 186 patients (74%) with angina at baseline became angina-free, and an additional 23 (9%) reduced their angina severity from limiting to mild. Twenty four patients (3%) who were angina free at baseline reported symptoms of angina at 3 months. Overall, there was significantly more improvement in angina than worsening of angina ($p < 0.01$)." The 12 week follow-up data were available for 1047 of the 1152 patients (91%). The authors stated: "In conclusion, the observed improvements in angina in patients making intensive lifestyle changes could drastically reduce their need for revascularization procedures." In this study, there was no comparison group. Primary outcome was self reported. Long term results were not reported. The program was administered by insurance companies.

Koertge J, Weidner G, Elliott-Eller M, Scherwitz L, Merritt-Worden TA, et al. Improvement in medical risk factors and quality of life in women and men with coronary artery disease in the Multicenter Lifestyle Demonstration Project. Am J Cardiol 2003;91:1316–1132.

In this case series/quasi-experimental study, the authors evaluated the 12-month outcome of 440 patients with baseline coronary artery disease who all participated in Ornish's Multicenter Lifestyle Demonstration Project (MLDP). Outcome measures included behavioral changes, including diet, exercise and mental health as well as cardiac risk factor changes, quality of life and psychosocial outcomes. Patients were enrolled either through self-referral in response to advertisements, or via referral by their physician. The intervention included exercise, CV risk factor modification (including diet, with consumption of 10% or less of total calories from fat), psychosocial assessment, and outcomes assessment. A multidisciplinary intervention team was involved, including a program director, medical director, exercise physiologist, stress management specialist, registered nurse as case manager, group support leader, registered dietitian, chef, and data manager.

Participants (who had been involved in the "intervention arm" of the MLDP) were classified into two groups. Group 1 contained people who had been diagnosed with CAD angiographically or by a PET scan, stress thalium or echo tests, showing enough ischemia to qualify for either CABG or PTCA according to Mutual of Omaha criteria for insurance coverage (e.g. ischemia with 3-vessel coronary disease and exercise-induced left ventricular dysfunction with ejection fraction less than 50%). Group 2 consisted of those participants who had previous CABG or PTCA, but were in stable condition at baseline. The authors also mention that a control group, matched to intervention group participants' characteristics, was also separately analyzed.

Statistical analysis utilized t-tests for continuous variables, and chi-square tests for categorical variables in comparing men and women regarding baseline factors. Also, analyses of variance for repeated measures were run to test for effect of both gender and time on medical and psychosocial measures, program attendance, and health behaviors. Mean age was 58 for men, 59 for women; more women than men had a diagnosis of diabetes (39% of 93 women vs. 16% of 347 men). Also, 194 patients (44% of men, 43% of women) were approved for a revascularization procedure, and 246 patients (56% of men, 57% of women) had a previous revascularization procedure.

Significant improvements, with some significant differences between men and women, occurred in multiple cardiac risk factors from baseline to 3-month follow-up, including: systolic blood pressure (132 to 127 in men, 135 to 129 in women, p (Time) = 0.001); diastolic blood pressure (79 to 74 in men, 79 to 76 in women, p (Time) < 0.001); body weight in kg (87 to 83 in men, 77 to 73 in women, p (Time) < 0.001); total serum cholesterol (195 to 177 mg/dL in men, 218 to 204 in women, p (Time) < 0.001); and LDL cholesterol (120 to 101 mg/dL in men, 132 to 115 in women, p (Time) < 0.001). These improvements in risk factors were visible at 3 months, and were maintained at 12 months. Quality of Life Score, measured via the MOS SF-36 questionnaire, also improved in both men and women in all categories measured (e.g. physical, emotional and social functioning).

The authors concluded that "the results of the MLDP demonstrate that a multi-component cardiac rehabilitation program focusing on diet, exercise, stress management, and social support can be successfully implemented at hospitals in diverse regions of the United States, with demonstrated benefits for both genders." Risk factor levels in the MLDP were similar to those observed in the earlier Lifestyle Heart Trial after one-year participation in the program.

Ornish D. Avoiding Revascularization with Lifestyle Changes: The Multicenter Lifestyle Demonstration Project. Am J Cardiol 1998;82:72T-76T.

In evaluating his Multicenter Lifestyle Demonstration Project (MLDP), Ornish used a prospective cohort design to follow 333 participants (194 in experimental group, 139 in control group) over a 3-year time period. The main outcome was the number of people in the experimental group who were able to avoid a revascularization procedure, in comparison to the number in the control group. At baseline, all participants had angiographically documented coronary artery disease, severe enough to justify revascularization (and approved by insurance). The participants were recruited from 8 different sites, which the author maintains are "geographically, socioeconomically, racially and culturally diverse." The MLDP contained diet and exercise components, as well as outcomes assessment (as explained in summary of Koertge, et al. 2003 study above). Regarding intensity, the program required at least 12 hours/week of scheduled exercise, diet, group support, and stress management. All control group patients were within one month of having had a revascularization procedure. Statistical analysis is not explained in detail in this study. Strict exclusion criteria were used, and patients were matched for several variables, including age, gender, left ventricular ejection fraction and cardiac score (varying with degree of stenosis in the main coronary arteries).

In looking at baseline demographics of study participants, the experimental and control groups had no statistical differences in the measures assessed. In the experimental group, average age was 58, 79% were male, 77% were married, and 64% were currently working. Many participants also had significant comorbid conditions. In the intervention group: 50% were hypertensive, 62% had hyperlipidemia, 20% had diabetes. Angiographic severity of coronary artery disease was comparable in the two groups, except that people in the intervention group were somewhat more likely to have had a myocardial infarction, and more likely to have a longer history of CAD.

In summarizing the results of the intervention on outcomes, Ornish found that 150/194 of experimental group patients were able to avoid revascularization, without any accompanying increase in the frequency of adverse cardiac events. When comparing the experimental group to the control group, the number of cardiac events per patient-year of follow-up was as follows: 0.012 vs. 0.012 for myocardial infarction; 0.014 vs. 0.006 for stroke; 0.006 vs. 0.012 for non-cardiac deaths; and 0.014 vs. 0.012 for cardiac deaths. P-values were reported as "not significant" for the above comparisons. Also, after 3 years, looking only at those patients in the experimental group who had initially reported having angina pain, 61% reported having no chest pain during the prior 30 days. Ornish maintains that this number is comparable to results of revascularization (no comparison values are listed). In addition, in assessing changes in cardiac risk factors, he noted significant improvement in the following at 3-year follow-up: LDL cholesterol (122.9 mg/dL at baseline to 101.7 at 3 years, $p<0.0001$); total cholesterol (202.0 to 183.4 mg/dL, $p < 0.0001$); HDL cholesterol (36.7 to 42.2 mg/dL, $p = 0.001$; weight (187.3 to 179.9 lbs, $p = 0.007$; exercise capacity (9.59 METS at baseline to 11.03 after 3 years, $p<0.0001$). Ornish concluded that as a result of the MLDP, "we found that experimental group patients were able to avoid revascularization for at least 3 years by making comprehensive lifestyle changes at substantially lower cost without increasing cardiac morbidity and mortality."

Ornish D, Brown SE, Scherwitz LW, Billings JH, et al. Can lifestyle changes reverse coronary heart disease? The Lifestyle Heart Trial. Lancet 1990; 336:129-33.

In the Lifestyle Heart Trial, Ornish and colleagues performed a randomized controlled trial to determine whether their lifestyle modification intervention could lead to improvements in cardiac risk factors and coronary artery stenosis. Forty eight patients, 28 in the experimental group and 20 in the control group, were followed for one year for changes. All participants had angiographically confirmed coronary artery disease, and had quantitative coronary angiography performed both at baseline and after approximately one year. Patients were recruited from two different hospitals in California, and met several different criteria including age 35-75 (mean age was 56 in intervention group, 60 in controls); no other life-threatening illnesses; no myocardial infarction in the past 6 weeks; and permission for participation in study granted by patient's cardiologist and primary care physician. More men than women were enrolled in the study (21/22 of experimental group were men, as were 15/19 of control group). Differences in baseline characteristics between the two groups were compared using conventional t-tests. Comparison of the two study groups' coronary artery lesion characteristics at baseline and after intervention was performed using a mixed-model analysis of variance. The intervention contained diet, exercise and outcomes assessment, as well as twice-weekly group support sessions. Participants were asked to eat a low-fat vegetarian diet for at least one year, and to participate in stress management techniques (e.g. breathing techniques, meditation) for at least one hour per day, assisted also by a one-hour audiocassette. Also, individually prescribed exercise levels were determined for each participant. They were asked to exercise for at least three hours per week, spending at least 30 minutes per session exercising within their target heart rate.

At baseline, the two groups were not significantly different in terms of demographic characteristics, diet and lifestyle characteristics, functional status, cardiac history or risk factors. The authors found that participants adhered well to the intervention, and noted significant improvements in LDL cholesterol and in weight between baseline and 12-month follow-up (for LDL, 3.9 to 2.5 mmol/L in experimental group, 4.3 to 4.1 mmol/L in controls ($p = 0.007$); for weight 91.1 kg to 81.0 kg in experimental group, 80.4 kg to 81.8 kg in controls ($p < 0.0001$)). Regarding the primary outcome, Ornish and colleagues also noted a decrease in average percent diameter stenosis (when comparing baseline to 12-month follow-up), from 40.0% to 37.8% in the intervention group, but a progression of stenosis in the control group, changing from 42.7% to 46.1% ($p = 0.001$, two-tailed). The difference was also significant when analyzing only those lesions with greater than 50% stenosis. Significant improvement in severity of angina symptoms also occurred in the intervention group compared with controls, and in comparing baseline to 12-month follow-up. Using a scale of 1 to 7, 1 being least severe, chest pain severity decreased from 2.3 to 1.7 in experimental group, and increased from 1.8 to 2.5 in controls ($p = 0.0006$).

In conclusion, Ornish and colleagues reported that this clinical trial has shown that "a heterogeneous group of patients with coronary heart disease can be motivated to make comprehensive changes in lifestyle for at least a year outside hospital." Also, "the strong relation between programme adherence and lesion changes showed that most patients needed to follow the lifestyle programme as prescribed to show regression." Additionally they stated that these findings suggest that "gender may affect progression and regression of atherosclerosis," and they pointed out that "the severely stenosed lesions showed the greatest improvement."

Ornish D, Scherwitz LW, Billings JH, Gould KL, et al. Intensive lifestyle changes for reversal of coronary heart disease. JAMA 1998;280:2001-2007.

In this randomized controlled trial, Ornish and colleagues randomized 48 patients with moderate to severe coronary heart disease (documented by coronary arteriography) to an intensive lifestyle change group or to a usual-care control group. Patients were followed for 5 years, with 35 of the 48 initially recruited patients undergoing baseline, 1-year and 5-year follow-up quantitative coronary arteriography. The intervention, based on the earlier Lifestyle Heart Trial of 1990, included exercise, cardiac risk factor modification, group psychosocial support, stress management training, and outcomes (but not psychosocial) assessment. The authors also used the same design, recruitment and study population as in the 1990 study. Importantly, all participants had coronary atherosclerosis documented by quantitative coronary arteriography. Percent diameter stenosis was chosen to be the primary dependent variable. Analysis of adherence variables and risk factor levels used time-structured repeated measures to incorporate levels from all 3 measurement times (baseline, 1 year and 5 years) into a single regression model.

Mean age was 57 in the experimental group, 62 in controls. Mean BMI at baseline was 28 in intervention group, 25 in controls, and many in the group had a history of myocardial infarction (12/20 in intervention, 5/15 in controls) and of reported angina (11 in intervention group, 6 controls). The average percent diameter stenosis significantly decreased in the experimental group by 1.8 absolute percentage points after 1 year and by 3.1 absolute percentage points after 5 years. In contrast, the percent stenosis significantly increased in the control group, by 2.3 percentage points at 1 year, and 11.8 percentage points at 5 years ($P = 0.02$ at 1 year, $P = 0.001$ at 5 years). Looking at cardiac risk factor changes, the authors found that weight loss was significant in the experimental group (91.4 kg at baseline, 85.6 kg at 5 years) but not in controls (75.7 kg at baseline, 77.1 kg at 5 years; $p = 0.001$). Both total cholesterol (5.8 to 4.2 mg/dL in experimental group, 6.4 to 6.3 in controls; $p = 0.004$) and LDL cholesterol (3.7 to 2.2 mg/dL in experimental group, 4.30 to 4.25 in controls; $p = 0.003$) also improved significantly in the intervention group compared with controls at 1 year. This difference in lipids was not seen at 5 years, which the authors attributed to the starting of anti lipid medications in 9/15 of the control participants. Finally, the rate of cardiac events was significantly improved in intervention vs. control participants, including risk of obtaining angioplasty ($p < 0.05$), cardiac hospitalization ($p < 0.001$) or "any event" ($p < 0.001$).

The authors concluded that their findings "support the feasibility of intensive lifestyle changes in delaying, stopping, or reversing the progression of coronary artery disease in ambulatory patients over prolonged periods." These patients, in contrast to the controls, "were able to make and maintain comprehensive changes in diet and lifestyle for 5 years and showed even more regression of coronary atherosclerosis after 5 years than after 1 year as measured by percent diameter stenosis."

Ornish D, Scherwitz LW, Doody RS, Kesten D, McLanahan SM, et al. Effects of stress management training and dietary changes in treating ischemic heart disease. JAMA 1983;249:54-59.

Ornish and colleagues reported the 24 day results of a randomized controlled trial "to evaluate the short-term effects of an intervention that consists of stress management training and dietary changes in patients with ischemic heart disease (IHD)." A total of 48 patients with evidence of IHD by angiography or radionuclide (pertechnetate) exercise testing were randomly assigned to an experimental group that received an intensive lifestyle modification program or a control group that continued routine activities. The experimental program included stress management training, exercise, meditation, rural environment, vegan diet, and nutrition counseling. Outcomes included exercise duration, plasma lipid levels, frequency of angina, ejection fraction response, regional wall motion, and medication changes. Inclusion criteria included age 45-75 years, > 50% stenosis of one or more coronary arteries, or a positive exercise stress test. Exclusion criteria included resting ejection fraction < 40%, myocardial infarction in prior 6 months, cancer, stroke, and prior coronary artery bypass surgery. Mean age was about 59 years. Men comprised 78% of the study. One patient withdrew from each group.

The authors reported "After 24 days, patients in the experimental group demonstrated a 44% mean increase in duration of exercise, a 55% mean increase in total work performed, somewhat improved left ventricular regional wall motion during peak exercise, and a net change in left ventricular ejection fraction from rest to maximum exercise of +6.4%." They concluded "In this selected sample, short-term improvements in cardiovascular status seem to result from these adjuncts to conventional treatments of IHD." In this study, the sample size was small. Long term results were not available. Patients in the experimental group were housed together in a rural environment.

Pischke CR, Weidner G, Elliott-Eller M, Ornish D. Lifestyle changes and clinical profile in coronary heart disease patients with an ejection fraction of ≤40% or >40% in the Multicenter Lifestyle Demonstration Project. European Journal of Heart Failure 2007;9:928–934.

Pischke and colleagues reported the results of a sub-analysis of the Multicenter Lifestyle Demonstration Project (MLDP) to "investigate the feasibility of intensive lifestyle changes for CHD (coronary heart disease) patients at risk for HF (heart failure)." A subgroup of 236 patients from the intervention group of the MLDP (Ornish, 1998) was analyzed. Outcomes included risk factor reduction and quality of life. Patient selection criteria were not reported. Mean age was approximately 58 years. Men comprised 82% of the study population. Of the 236 patients, 50 (21%) had left ventricular ejection fraction (LVEF) ≤ 40% and 186 had LVEF > 40%. Follow-up assessments were performed at 12 weeks.

The authors reported "Regardless of LVEF, patients showed significant improvements (all pb.05) in lifestyle behaviours, body weight, body fat, blood pressure, resting heart rate, total and LDL-cholesterol, exercise capacity, and quality of life by 3 months; most improvements were maintained over 12 months." They concluded "CHD patients at risk for heart failure with an LVEFV40% can make changes in lifestyle to achieve similar medical and psychosocial benefit to patients with an LVEFN40%."

Silberman A, Banthia R, Estay IS, Kemp C, Studley J, Hareras D, Ornish D. The effectiveness and efficacy of an intensive cardiac rehabilitation program in 24 sites. Am J Health Promot 2010;24:260–266.

Silberman and colleagues reported the results of an analysis of patients who participated in the Ornish program "to test the efficacy and effectiveness of an intensive cardiac rehabilitation program in improving health outcomes in multiple sites." A total of 2974 patients participated in the program offered by Highmark at 24 sites from 1998 to 2009. As described by Frattaroli (2008) and Daubenmier (2007) (Multisite Cardiac Lifestyle Intervention Program), all participants had diagnosed coronary artery disease. The intervention consisted of 4 components: "healthy diet, moderate physical activity, psychosocial group support, and stress management techniques." As described by the authors, "participants were instructed to eat a low-fat, whole-foods, plant-based diet (fruits, vegetables, whole grains, legumes, soy products) low in refined carbohydrates, exercise for a minimum of 3 h/wk (e.g., walking), attend group support meetings, and practice stress management techniques such as restorative yoga and meditation for 1 h/d. Patients were encouraged to continue following these guidelines for at least 1 year. Patients were asked to attend an 8-hour orientation as well as 4-hour sessions held twice a week for 12 weeks that included group support, didactic lectures, cooking demonstrations, supervised exercise, guided stress management sessions, case management, and a group meal. After 12 weeks, participants were stratified based on clinical profiles into groups that received ongoing stress management and group support for 2 hours once a week for up to 40 additional weeks, depending on level of risk. All participants were encouraged to meet weekly in a self-directed community for the remainder of the year in which they continued these 2-hour sessions on their own, and also received monthly case management calls from a nurse for the remainder of the year." Mean age was 59 years. Men comprised 48% of the study population. Paired t-tests were used for analysis.

The authors reported significant improvements in body mass index (BMI), triglycerides, low density lipoprotein cholesterol, total cholesterol, hemoglobin A1c, systolic blood pressure, diastolic blood pressure, depression, hostility, exercise, and functional capacity" at 12 weeks and 1 year. They concluded: "This intensive cardiac rehabilitation program was feasible and sustainable for most patients who enrolled and was associated with numerous subjective and objective improvements in health outcomes. It demonstrates that the intervention works when it is administered by staff at multiple clinical/community sites in four different states. These improvements were also seen in patients 65 years of age or older." There was no comparison group. Complete 1 year data were available for less than 50% of the participants. The main reason for missing data was change in insurance coverage.

4. MEDCAC

No Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) was convened for this issue.

5. Evidence-based guidelines

No evidence-based guidelines specific to the Ornish program were found.

6. Professional Society Position Statements

No professional society position statements specific to the Ornish program have been released.

7. Public Comments

During the initial 30-day public comment period CMS received five comments. Three of the comments were supportive of coverage, and two were less supportive, offering more critique and commentary.

During the 30-day public comment period following the release of the proposed decision memorandum, we received 31 comments. The comments, with and without evidence, are summarized below. CMS responses are provided in italics.

Comments with New Evidence

Commenters cited five articles as evidence not previously reviewed. After reviewing the articles, they were not incorporated into the analysis because one focused on costs and enrollment in the Ornish program rather than health outcomes and four were limited to the dietary component rather than the full program.

Barnard et al., 2006; Berkow et al., 2005; Jenkins et al., 2003
Comment: One commenter notes the benefit of the diet component of the Ornish program by citing these three studies which show that low-fat vegetarian diets, similar to the diet utilized in the Ornish program, can lead to significant improvements in cholesterol, blood pressure, and weight loss.

CMS Response: We agree that the improvements demonstrated by the Ornish program in available evidence support coverage and have decided to finalize our proposed decision.

Dansinger et al., 2005
Comment: One commenter cites this direct comparative study of the Ornish program and three other commercial weight loss programs to question whether available evidence is "sufficiently robust" enough to distinguish the Ornish program from or recommend it over other commercially available programs. This commenter notes that this study found that "weight loss and impact on cardiac risk factors was similar with the Ornish Program as with the other popular diet programs," compliance was low with all three programs and completion concerns existed with the Ornish program.

CMS Response: As noted in section III, the Medicare statute and regulations set forth specific standards that must be satisfied in order for an ICR program to be approved. Neither the statute nor regulations require an ICR program to be compared to another program. Any program that meets the statutory and regulatory requirements, as demonstrated by peer-reviewed published research, may be recognized. The commenter has not presented any evidence that the Ornish program does not meet the applicable criteria.

Shepard et al., 2009
Comment: One commenter cites the Medicare demonstration project that examined the Ornish program to question CMS' proposed decision. This commenter contends that the demo found that it was extremely difficult to sign up enrollees in the Ornish program; the Ornish program was significantly more expensive than traditional CR but rehospitalization (at 12 months), mortality (at 36 months), or first time to cardiovascular hospitalization in Ornish patients showed no statistical improvements over matched patients in traditional CR or those not participating in CR.

CMS Response: The specific issues identified by this commenter are not included in the statutorily required ICR program requirements. Thus, these issues are not relevant to our final decision.

Comments without New Evidence

Comment: Two commenters support coverage of the Ornish program by citing articles we have already reviewed in the proposed decision memorandum.

CMS Response: We agree that the improvements demonstrated by the Ornish program in available evidence support coverage and we have decided to finalize our decision as proposed.

Comments: Thirty commenters support the proposed decision to include the Ornish program as a covered ICR program. Many commenters are enthusiastic in support for the program. Two commenters assert that evidence shows that the Ornish program meets the accomplishments and improvements required in the regulation. One commenter contends that the Ornish evidence is important and accurate; one commenter asserts that evidence shows that the program can delay or prevent progression of heart disease, and one commenter states that the program is life changing.

CMS Response: We appreciate the public comments. We have finalized the proposed decision to include the Ornish program as a covered ICR program under Medicare part B.

Comments: One commenter suggests that CMS pay for food under the Ornish program and one commenter recommends that Medicare help patients maintain CR training. One requests that CMS increase the payment rate for ICR services.

CMS Response: These issues are outside the scope of this NCD.

Comment: One commenter requests clarification on how programs similar to the Ornish program may become approved and asserts that it would be reasonable for smaller programs without their own peer-reviewed published research to submit their own unique outcomes data and "rely on the same published data to meet the legislative criteria for approval."

CMS Response: All ICR programs must be approved by CMS through the NCD process and are subject to the same requirements in §1861(eee)(4)(A) of the Social Security Act and in our regulations at 42 C.F.R. §410.49(c). Each ICR program that is evaluated via the NCD process must have peer-reviewed published research specific to the exact program under evaluation in order for CMS to undertake a national coverage analysis (NCA).

Comments: One commenter questions how the Ornish program will be able to be replicated and implemented nationally, exactly what components of the program CMS will cover, and how an entity will become licensed/certified to furnish services under the Ornish program.

CMS Response: Medicare's ICR regulation specifies the required program components – physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment. See 42 C.F.R. §410.49. The final rule sets forth procedures for a prospective ICR site to apply to enroll in the Medicare program to furnish these services. See 42 C.F.R. §410.49(c)(4).

VIII. CMS Analysis

This national coverage determination (NCD) is a scope of benefit determination and is made by the Secretary with respect to whether or not a particular ICR program meets the coverage requirements under title XVIII of the Social Security Act. §1861(eee)(4). Congress specifically authorized coverage of ICR if certain criteria are met as described in Section III of this document.

For this analysis, we addressed the following question:

Does the Ornish Program for Reversing Heart Disease (also known as the Multisite Cardiac Lifestyle Intervention Program, Multicenter Cardiac Lifestyle Intervention Program and the Lifestyle Heart Trial program) meet the requirements set forth in §1861(eee)(4) for an ICR program:

(1) positively affected the progression of coronary heart disease;
(2) reduced the need for coronary bypass surgery; and
(3) reduced the need for percutaneous coronary interventions?

As required by §1861(eee)(4)(A)(ii) of the Act, an ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and (6) the need for cholesterol, blood pressure, and diabetes medications.

Progression of coronary heart disease, reduction in the need for coronary bypass surgery, and/or reduction in the need for percutaneous coronary interventions.

The Lifestyle Heart Trial (5 year results reported by Ornish et al., JAMA 1998; 1 year results reported by Ornish et al., Lancet 1990) showed significant regression of coronary atherosclerosis measured by angiography in the experimental group randomly assigned to intensive lifestyle changes. Although the Lifestyle Heart Trial had a small sample size (n = 43), it used a random assignment and the readers of the arteriograms were blinded. The Multicenter Lifestyle Demonstration project (Ornish et al., 1998) showed that participation in the program with comprehensive lifestyle changes was associated with a reduction in revascularization at the 3 year follow-up. Although this study was not a randomized trial, it had a larger sample size, was conducted in more sites, and supported the results of the Lifestyle Heart Trial. These two published studies provided evidence that participation in the Ornish program positively affected the progression of coronary heart disease and reduced the need for bypass surgery and percutaneous angioplasty.

Dean Ornish, MD, the founder and director of the Ornish Program, was closely involved with many of the studies and reports evaluated in this analysis and as such, his direct financial interest in the program is important to consider. Despite this financial consideration that could possibly impact the objectivity of the science, CMS feels that these studies and reports offer scientifically valid information and are important for this evidence review. We also considered other peer-reviewed published research in which Dr. Ornish played a limited or no role.

Statistically significant reduction in 5 or more of the following measures: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and (6) the need for cholesterol, blood pressure, and diabetes medications.

The Multisite Cardiac Lifestyle Intervention Program (Daubenmeir et al., 2007; Frattaroli et al., 2008; Silberman et al., 2010) showed significant reductions in low density lipoprotein, triglycerides, weight (component of body mass index), systolic blood pressure, and diastolic blood pressure. The Multicenter Lifestyle Demonstration Project (Ornish et al., 1998; Koertge et al., 2003) showed significant reductions in low density lipoprotein, triglycerides, and weight (component of body mass index). The Lifestyle Heart Trial (5 year results reported by Ornish et al., 1998; 1 year results reported by Ornish et al., 1990) showed significant reductions in low density lipoprotein and body mass index. An early trial (Ornish et al., 1983) also showed significant reductions in triglycerides, frequency of angina, and reduction in antihypertensive medications. Considered together, these published studies provided evidence that participation in the Ornish program led to significant reductions in these cardiac risk factors.

Based upon evidence published in the medical literature, the Ornish Program for Reversing Heart Disease (also known as the Multisite Cardiac Lifestyle Intervention Program, Multicenter Cardiac Lifestyle Intervention Program and the Lifestyle Heart Trial program), meets the requirements set forth in MIPPA for an ICR program. Including the Ornish program as a covered ICR program will increase access to ICR services for Medicare beneficiaries and subsequently reduce the disparate impact of heart disease in minority populations. Such increased access will continue one of Medicare's very important missions to decrease disparities amongst beneficiaries.

IX. Conclusion

The Centers for Medicare and Medicaid Services (CMS) has determined that the Ornish Program for Reversing Heart Disease meets the intensive cardiac rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act and in our regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/MedicareApprovedFacilitie/.

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* Denotes citations referenced by public commenters. CMS reviews all public commenters' citations and includes relevant articles in the evidence review.
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